Attorney Docket No.: PTI-001CN Express Mail Label No. EV 093437167 US

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**APPLICANT:** 

Kornblith

**SERIAL NO.:** 

09/040,161

**GROUP NO.:** 

1651

**FILING DATE:** 

March 17, 1998

**EXAMINER:** 

Gitomer, R.

TITLE:

Method for Preparing Cell Cultures from Biological Specimens for

**Chemotherapeutic and Other Assays** 

Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified application. Copies of the patents (A1-A22, B1) and publications (C1-C37) on the accompanying Form PTO-1449 are submitted herein.

In accordance with the provisions 37 C.F.R. § 1.97, this statement is being filed before the mailing of a first Office action after the filing of a Request for Continued Examination. It is respectfully requested that each of the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, be made of record in this application.

Additionally, as requested by the Examiner, the following table lists Applicant's related U.S. utility applications, allowed, pending, and abandoned. It is respectfully requested that Applicant's related U.S. applications be made of record for consideration by the Examiner in connection with the examination of the above-identified application.

Attorney Docket No.	Patent/ Serial No.	Priority Information	Title	Filing Date	Issue Date/ Status	Inventor(s)
PTI-001	5,728,541	Parent	"Method of Preparing Cell Cultures From Biological Specimens for Chemotherapeutic and Other Assays"	12-Jul-1996	17-Mar-1998	Kornblith
PTI-001CN	09/040,161	CN of 5,728,541	"Method for Preparing Cell Cultures from Biological Specimens for Chemotherapeutic and Other Assays"	17-Mar-1998	Pending	Kornblith
PTI-001CN2	10/205,887	CN of 09/040,161	"Method for Preparing Cell Cultures From Biological Specimens for Chemotherapeutic and Other Assays"	26-Jul-2002	Pending	Kornblith
PTI-002	09/039,957	CIP of 09/040,161	"Method for Culturing and Assaying Cells"	16-Mar-1998	Pending	Kornblith
PTI-003	09/095,993	CIP of 09/040,161	"Staining Agents and Protocols for Characterizing Malignant Cells in Culture"	11-Jun-1998	Pending	Naus Kornblith Burholt Meyer
РТІ-004	6,416,967	CIP of 5,728,541 CIP of 09/095,993 CIP of 09/039,957	"Method for Using Multicellular Particulates to Analyze Malignant or Hyperproliferative Tissue"	10-Nov-1998	08-Jul-2002	Kornblith
PTI-005	09/691,492	CIP of 09/095,993 CIP of 09/039,957 CIP of 6,416,967	"Method for Genetic Analysis of Proliferating Cells"	18-Oct-2000	Pending	Komblith
PTI-005CP	10/399,563	CIP of 09/691,492 (371 Filing of PCT/US01/32540)	"Method for Tandem Genomic/ Proteomic Analysis of Proliferating Cells"	17-Apr-2003	Pending	Kornblith Donovan- Peluso

### **CONCLUSION**

Applicant respectfully requests that each of the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, be made of record and consideration by the Examiner in connection with the examination of this application.

Respectfully submitted,

Dated: February 6, 2004

Reg. No. 50,794

Attorney for Applicant

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**FORM PTO - 1449** 

#### INFORMATION DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: PTI-001CN

APPLICANT: Kornblith

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#### U.S. PATENT DOCUMENTS CLASS SUB FILING DATE IF DOCUMENT DATE NAME EXAM. NUMBER CLASS APPROPRIATE INIT. 12-27-1983 Stampfer et al. Αi 4,423,145 A2 4,668,618 05-26-1987 Thornthwaite 05-26-1990 4,937,187 Rotman A3 02-26-1991 Weisenthal A4 4,996,145 5,242,806 09-07-1993 Yen-Maguire et al. Α5 12-14-1993 A6 5,270,172 Morgan A7 5,443,950 08-22-1995 Naughton et al. 03-04-1997 Eriksson et al. A8 5,607,918 Kornblith 5,728,541 03-17-1998 Α9 A10 5,789,158 08-04-1998 Knowles et al. 5,874,218 02-23-1999 Drolet et al. All 5,888,765 03-30-1999 Patterson et al. A12 5,942,385 08-24-1999 Hirth A13 Parandoosh A14 5,972,639 10-26-1999 Fruehauf et al. A15 6,008,007 12-28-1999 02-01-2000 A16 6,020,473 Keyt et al. 07-17-2001 Fruehauf et al. A17 6,261,795 A18 6,303,324 10-16-2001 Fruehauf et al. 01-01-2002 Orntoft A19 6,335,170 07-09-2002 Kornblith A20 6,416,967 01-28-2003 Fruehauf et al. A21 6,511,806 A22 2003/0096290 A1 05-22-2003 Fruehauf et al. DATE CONSIDERED **EXAMINER**

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INFORMATION DISCLOSURE STATEMENT			APPLICANT: Kornblith  SERIAL NO.: 09/040,161  FILING DATE: March 17, 1998 GROUP: 1651														
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								EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG
	B1	WO 96/10742	04-11-1996	WO													
			OTHER A	RT, JOURN	NAL ART	ICLES, E	TC.	.,									
EXAM. INIT.	отні	ER DOCUMENT	S: (Including	Author, Title	e, Date, Relo	evant Page	s, Place of I	Publication)									
	CI	Alley, M., et al. Sensitivity in So							h and Drug								
	C2	Andreotti, P., <i>et al.</i> , "TCA-100 Tumour Chemosensitivity Assay: Differences in Sensitivity between Cultured Tumour Cell Lines and Clinical Studies," Journal of Bioluminescence and Chemiluminescence, vol. 9, pp. 373-378 (1994).															
	С3	Arnold, J., et al., "Evaluation of Chemopreventative Agents in Different Mechanistic Classes Using a Rat Tracheal Epithelial Cell Culture Transformation Assay," Cancer Research, vol. 55, pp. 537-543 (1995).															
	C4	Bosanquet, A., "Short-term <i>In Vitro</i> Drug Sensitivity Tests For Cancer Chemotherapy. A Summary of Correlations of Test Result With Both Patient Response and Survival," FORUM 4.2, pp. 179-195 (1994).  Broadley, C., <i>et al.</i> , "A Tissue-Culture Model for the Study of Canine Vocal Fold Fibroblasts," Laryngoscope, vol. 105, no. 1, pp. 23-27 (1995).  Burczynski, M., <i>et al.</i> , "Toxicogenomics-Based Discrimination of Toxic Mechanism in HepG2 Human Hepatoma Cells," Toxicological Sciences, vol. 58, no.2, pp. 399-415 (2000).															
	C5																
	C6																
	C7	Cilley, R., <i>et al.</i> , "Fetal Lung Development: Airway Pressure Enhances the Expression of Developmental Genes," Journal of Pediatric Surgery, vol. 35, no. 1, pp. 113-119 (2000).															
	C8	Dietel, M., et al., "In Vitro Prediction of Cytostatic Drug Resistance in Primary Cell Cultures of Solid Malignant Tumours," Eur. J. Cancer, vol. 29A, no. 3, pp. 416-420 (1993).															
· · · · · · · · · · · · · · · · · · ·	C9	Dudley, D., et al., "A Human Endometrial Explant System: Validation and Potential Applications," Am. J. Obstet. Gynecol., vol. 167, no. 6, pp. 1774-1780 (1992).  Fruehauf, J., "In Vitro Assay-assisted Treatment Selection For Women With Breast or Ovarian Cancer," Endocrine-Related Cancer, vol. 9, pp. 171-182 (2002).  Frykholm, G., et al., "Heterogeneity in Antigenic Expression and Radiosensitivity in Human Colon Carcinoma Cell Lines," In Vitro Cell Dev. Biol., vol. 27A, pp. 900-906 (1991).															
	C10																
	CH				olon												
	C12	Fulda, S., et al., "Antiproliferative Potential of Cytostatic Drugs on Neuroblastoma Cells <i>In Vitro</i> ," Eur. J. Cancer, vol. 31A, no. 4, pp. 616-621 (1995).			itro," Eur. J.												
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INFORMATION DISCLOSURE STATEMENT		APPLICANT: Kornblith			
		SERIAL NO.: 09/040,161			
		FILING DATE: March 17, 1998 GROUP: 1651			
C13	Gamboa, G., et al., "Characterization and Development of UCI 107, a Primary Human Ovarian Carcinoma Cell Line," Gynecologic Oncology, vol. 58, pp. 336-343 (1995).				
C14	Gerweck, <i>et al.</i> , "Radiation Sensitivity of pp. 231-234 (1977).	Cultured Human Glioblastoma Cells," Radiology, vol. 125, no. 1			
C15		aining of Reactive Mesothelium, Mesothelioma, and Lung ntibodies," J. Clin. Pathol., vol. 40, pp 19-25 (1987).			
C16		ing Procedures, and Design of Cell Proliferation Studies Relating to erspectives, vol. 101, supp. 5, pp. 59-66 (1993).			
C17	Gress, T., et al., "Development of a Database on Transcribed Sequences in Tumour Cells and Identification of Changes in Transcription Patterns Related to Transformation and Other Tumour Cell Properties for the Global Finger Printing Analysis of Human Pancreatic Carcinoma cDNA Libraries," Biomedl. Health Res., vol. 24, pp. 171-181 (1998).				
C18	Hoffman, R., "The Three-Dimensional Question: Can Clinically Relevant Tumor Drug Resistance be Measured <i>In Vitro</i> ?" Cancer and Metastasis Reviews, vol. 13, no. 2, pp. 169-173 (1994).				
C19	Kaaijk, P., et al., "Daunorubicin and Doxorubicin but not BCNU have Deleterious Effects on Organotypic Multicellular Spheroids of Gliomas," British Journal of Cancer, vol. 74, no. 2, pp. 187-193 (1996).				
C20	Kitamura, M., et al., "Chemosensitivty of Gastric Cancer Using Adhesive Tumor Cell Culture System," Oncology Reports, vol. 2, no. 1, pp. 27-31 (1995).				
C21	Kornblith, P., "Role of Tissue Culture in Prediction of Malignancy," Clinical Neurosurgery, vol. 25, pp. 346-376 (1978).				
C22	Kornblith, P., et al., "Variations in Response of Human Brain Tumors to BCNU <i>In Vitro</i> ," Journal of Neurosurgery, vol. 48, no. 4, pp. 580-586 (1978).				
C23	Kruczynski, A., et al., "Evidence of a Direct Relationship Between the Increase in the <i>In Vitro</i> Passage Number of Human Non-Small-Cell-Lung Cancer Primocultures and their Chemosensitivity," Anticancer Research, vol. 13, pp. 507-514 (1993).				
C24	McGuire, W., et al., "In vitro assays to Predict Drug Sensitivity and Drug Resistance, A Panel Discussion," Breast Cancer Research and Treatment, vol. 12, pp. 7-21 (1988).				
C25	Nance, K., <i>et al.</i> , "Immunocytochemical Panel for the Identification of Malignant Cells in Scrous Effusions," Am. J. Clin. Pathol., vol. 95, pp. 867-874 (1991).				
C26	Persons, D., et al., "Interphase Molecular Cytogenetic Analysis of Epithelial Ovarian Carcinomas," American Journal of Pathology, vol. 142, no. 3, pp. 733-741 (1993).				
C27	Pinkus, G., et al., "Optimal Immunoreactivity of Keratin Proteins in Formalin-Fixed, Paraffin-Embedded Tissue Requires Preliminary Trypsinization," Journal of Histochemistry and Cytochemistry, vol. 33, no. 5, pp. 465-473 (1985).				
EXAMINER		DATE CONSIDERED			

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INFORMATION DISCLOSURE STATEMENT		APPLICANT: Kornblith		
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C28	C28 Raju, G., "The Histological and Immunohistochemical Evidence of Squamous Metaplasia from the Myoepithelial Cells in the Breast," Histopathology, vol. 17, no. 3, pp. 272-275 (1990).			
C29	Robert, J., "Chemosensitivity Testing. Prediction of Response to Anticancer Drugs Using In Vitro Assays," Electronic Journal of Oncology, vol. 2, pp. 198-210 (1999).			
C30	Singh, H., et al., "Significance of Epithelial Membrane Antigen in the Work-Up of Problematic Serous Effusions," Diagnostic Cytopathology, vol. 13, no. 1, pp. 3-7 (1995).			
C31	Stephens, S., <i>et al.</i> , "A Longitudinal Study of γ-Interferon Production by Peripheral Blood Mononuclear Cells from Breast- and Bottle-Fed Infants," Clin. Exp. Immunol., vol. 65, pp. 396-400 (1986).			
C32	Stewart, R., <i>et al.</i> , "Glutamate Accumulation By Human Gliomas and Meningiomas in Tissue Culture," Brain Research, vol. 118, no. 3, pp. 441-452 (1976).			
C33	Stoop, J., et al., "Identification of Malignant Cells in Serous Effusions Using a Panel of Monoclonal Antibodies Ber-EP4, MCA-b-12 and EMA," Cytopathology, vol. 3, pp. 297-302 (1992).			
C34	Wiseman, I., "A Modification of Hepatest, using the Terasaki Plate, for the Detection of Hb <sub>s</sub> Ag in Blood Donors," J. Clin. Pathol., vol. 29, no. 3, pp. 264-266 (1976).			
C35	International Search Report for PCT/US01/32540 dated April 18, 2002.			
C36	International Search Report for PCT/US97/11595 dated August 17, 1998.			
C37	International Search Report for EP 97 93 3267 dated May 3, 2002.			
EXAMINER		DATE CONSIDERED		